## REMARKS

**INTRODUCTION:**

In accordance with the foregoing, claims 7 and 9-18 have been canceled without prejudice or disclaimer, and claim 6 has been amended. No new matter is being presented, and approval and entry are respectfully requested.

Claims 6 and 8 are pending and under consideration. Reconsideration is respectfully requested.

**CHANGES TO THE TITLE:**

In the Office Action, at page 2, numbered paragraph 4, a new title was required for clarity.

The title has been as suggested by the Examiner. Hence, it is respectfully submitted that the title is now in allowable form.

**REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH:**

**A.** In the Office Action, at pages 3-4, numbered paragraph 6, claims 6-8 were rejected under 35 U.S.C. §112, first paragraph, because the Examiner submitted: "the specification, while being enabling for the detection of chronic hepatitis, liver, cirrhosis and hepatocarcinoma with liver cirrhosis using mAbKCTC 10261 to detect AsAGP, does not reasonably provide enablement for the diagnosis of any and all liver diseases using any other monoclonal antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." This rejection is traversed and reconsideration is requested.

Claim 6 has been amended to include the features of claim 7 and to recite: "in which the monoclonal antibody is the subclass $IgG_1$ produced from the mouse cell line deposited with the accession number KCTC 10261 BP." Claim 7 has been canceled without prejudice or disclaimer.

An Affidavit is enclosed herewith verifying that As16.89 (lymphoblast-like hybridoma cell lines), assigned accession number KCTC 10261BP, has been deposited in the Korean Collection for Type Cultures, Korea Research institute of Bioscience and Biotechnology (KRIBB) #52, Oun-dong, Yusong-ku, Taejon 305-333, Republic of Korea, as International Depositary Authority as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on May 24, 2002; during the pendency of this application, access to the invention will be afforded to the Commissioner upon

request; all restrictions upon availability to the public will be irrevocably removed upon granting of the patent; the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; the deposits were viable at the time of deposit; and the deposits will be replaced if they should ever become non-viable.

Also, enclosed is a copy of the RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT for As16.89 (lymphoblast-like hybridoma cell lines), assigned accession number KCTC 10261BP, which has been deposited in the Korean Collection for Type Cultures, Korea Research institute of Bioscience and Biotechnoloty (KRIBB) #52, Oun-dong, Yusong-ku, Taejon 305-333, Republic of Korea, as International Depositary Authority as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on May 24, 2002.

Since the Examiner recited: "It would appear from this data that the specification is only enabled for the detection of chronic hepatitis, liver cirrhosis and hepatocarcinoma with liver cirrhosis using mAb KCTC 10261 and only when the detected level of AsAGP is above 1,50 µg/ml. The specification is not enabled for the diagnosis of any and all liver diseases using any monoclonal antibody except for MAb KCTC 10261," amended claim 6 is submitted to be enabling and in allowable form under 35 U.S.C. §112, first paragraph. Since claim 8 depends from amended claim 8, claim 8 is enabling and in allowable form under 35 U.S.C. §112, first paragrap, for at least the reasons amended claim 6 is enabling and in allowable form under 35 U.S.C. §112, first paragraph.

**B.** In the Office Action, at pages 4-7, numbered paragraph 8, claim 7 was rejected under under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 has been canceled without prejudice or disclaimer. Thus, the rejection of claim 7 is now moot.

**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH:**

In the Office Action, at pages 7-8, claims 6-8 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

Claim 6 has been amended for clarity (see above) and is submitted to be definite, to particularly point out and distinctly claim the subject matter which applicants regard as the invention, and to be allowable under 35 U.S.C. §112, second paragraph. Claim 7 has been

cancelled without prejudice or disclaimer. Since claim 8 depends from amended independent claim 6, claim 8 is definite, particularly points out and distinctly claims the subject matter which applicants regard as the invention, and is allowable under 35 U.S.C. §112, second paragraph, for at least the reasons amended independent claim 6 is definite, particularly points out and distinctly claims the subject matter which applicants regard as the invention, and is allowable under 35 U.S.C. §112, second paragraph.

**REJECTION UNDER 35 U.S.C. §102:**

**A.** In the Office Action, at page 8, numbered paragraph 13, claims 6-8 were rejected under 35 U.S.C. §102(f) because the Examiner submitted that the applicants did not invent the claimed subject matter. This rejection is traversed and reconsideration is requested.

Enclosed herewith is a Declaration Under 37 CFR 131, which states:

1. U.S. patent application Ser. No. 10/540,848, a national patent application filed based on WO 2004/058823, which claims a priority date of December 27,2002, is the work of Tai Wha CHUNG, Eun Young SONG, Ji Hyun KANG, Kyoung A. KIM, Eun Young LEE, and Yong Kyung CHOE.

2. Eun Young SONG, Kyoung A. KIM, Yung Dai KIM, Eun Young LEE, Hong Soo LEE, Hee Jung KIM, Byung Min AHN, Yong Kyung CHOE, Cheorl Ho KIM, and Tai Wha CHUNG are authors of "Elevation of serum asiolo-$\alpha_1$ acid glycoprotein concentration in patients with hepatic cirrhosis and hepatocellular carcinoma as measured by antibody-lectin sandwich assay," Hepatology Research, 26(2003), 311-317.

3. Tai Wha CHUNG, Eun Young SONG, Ji Hyun KANG, Kyoung A. KIM, Eun Young LEE, and Yong Kyung CHOE are inventors of the subject matter set forth in U.S. patent application Ser. No. 10/540,848, which is also described in "Elevation of serum asiolo-$\alpha_1$ acid glycoprotein concentration in patients with hepatic cirrhosis and hepatocellular carcinoma as measured by antibody-lectin sandwich assay," Hepatology Research, 26(2003), 311-317.

4. While Yung Dai KIM, Hong Soo LEE, Hee Jung KIM, Byung Min AHN, and Cheorl Ho KIM are authors of "Elevation of serum asiolo-$\alpha_1$ acid glycoprotein concentration in patients with hepatic cirrhosis and hepatocellular carcinoma as measured by antibody-lectin sandwich assay," Hepatology Research, 26(2003), 311-317, Yung Dai KIM Hong Soo LEE, Hee Jung KIM, Byung Min AHN, and Cheorl Ho KIM are not inventors of the subject matter of U.S. patent application Ser. No. 10/540,848.

Hence, it is respectfully submitted that it is clear that applicants did invent the claimed subject matter. Claim 7 has been canceled without prejudice or disclaimer. Claims 6 and 8 are submitted to be allowable under 35 U.S.C. §102(f).

**B.** In the Office Action, at page 9, numbered paragraph 14, claims 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Toyama et al. (EP 0199 196;hereafter, Toyama). This rejection is traversed and reconsideration is requested.

Amended independent claim 6 recites: "A method for diagnosing a liver disease in which a monoclonal antibody which reacts only with asialo α1-acid glycoprotein and excludes heptoglobin and α2-macroglobulin; and lectin RCA (Ricinus communis agglutinin) recognizing asialo glycoprotein are reacted with a test sample to measure the amount of asialo α1-acid glycoprotein (AsAGP), in which the monoclonal antibody is the subclass $IgG_1$ produced from the mouse cell line deposited with the accession number KCTC 10261 BP, wherein a cutoff value for diagnosing the liver disease is 1.50 μg/ml."

Hence amended independent claim 6 utilizes a monoclonal antibody which is the subclass $IgG_1$ produced from the mouse cell line deposited with the accession number KCTC 10261 BP, wherein a cutoff value for diagnosing the liver disease is 1.50 μg/ml. It is respectfully submitted that Toyama does not teach or suggest utilizing such an antibody.

Anticipation requires a lack of novelty of the invention as claimed. The invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior art reference, arranged as in the claim. See C.R. Bard, Inc. v. M3 Systems, Inc., 157 F3d 1340, 1349, 48 USPQ2d 1225, 1229-30 (Fed. Cir. 1998); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Hence, amended independent claim 6 is not anticipated under 35 U.S.C. §102(b) by Toyama et al. (EP 0199 196). Since claim 8 depends from amended independent claim 6, claim 8 is not anticipated under 35 U.S.C. §102(b) by Toyama et al. (EP 0199 196) for at least the reasons amended independent claim 6 is not anticipated under 35 U.S.C. §102(b) by Toyama et al. (EP 0199 196).

**C.** In the Office Action, at page 9, numbered paragraph 15, claims 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Fraeyman et al. (Hybridoma, 1987 Nol. 6, pp. 565-567; hereafter, Fraeyman). This rejection is traversed and reconsideration is requested.

Amended independent claim 6 recites: "A method for diagnosing a liver disease in which a monoclonal antibody which reacts only with asialo α1-acid glycoprotein and excludes heptoglobin and α2-macroglobulin; and lectin RCA (Ricinus communis agglutinin) recognizing

asialo glycoprotein are reacted with a test sample to measure the amount of asialo α1-acid glycoprotein (AsAGP), in which the monoclonal antibody is the subclass $IgG_1$ produced from the mouse cell line deposited with the accession number KCTC 10261 BP, wherein a cutoff value for diagnosing the liver disease is 1.50 μg/ml."

Hence amended independent claim 6 utilizes a monoclonal antibody which is the subclass $IgG_1$ produced from the mouse cell line deposited with the accession number KCTC 10261 BP, wherein a cutoff value for diagnosing the liver disease is 1.50 μg/ml. It is respectfully submitted that Fraeyman does not teach or suggest utilizing such an antibody.

Anticipation requires a lack of novelty of the invention as claimed. The invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior art reference, arranged as in the claim. See C.R. Bard, Inc. v. M3 Systems, Inc., 157 F3d 1340, 1349, 48 USPQ2d 1225, 1229-30 (Fed. Cir. 1998); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Hence, amended independent claim 6 is not anticipated under 35 U.S.C. §102(b) by Fraeyman et al. (Hybridoma, 1987 Nol. 6, pp. 565-567). Since claim 8 depends from amended independent claim 6, claim 8 is not anticipated under 35 U.S.C. §102(b) by Fraeyman et al. (Hybridoma, 1987 Nol. 6, pp. 565-567) for at least the reasons amended independent claim 6 is not anticipated under 35 U.S.C. §102(b) by Fraeyman et al. (Hybridoma, 1987 Nol. 6, pp. 565-567).

**D.** In the Office Action, at pages 9-10, numbered paragraph 16, claims 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Song et al. (Clinical Chemistry, Vo., 47, No. 6, Supplement, 2001, A152; hereafter, Song). This rejection is traversed and reconsideration is requested.

It is respectfully submitted that the present application is a national patent application filed based on WO 2004/058823, which claims a priority date of December 27,2002. Song was published in 2003. Hence, the invention was not described in a printed publication prior to the priority date of the invention, and Song is not a valid reference under under 35 U.S.C. §102(b).

Thus, claims 6 and 8 are not anticipated under 35 U.S.C. §102(b) by Song et al. (Clinical Chemistry, Vo., 47, No. 6, Supplement, 2001, A152).

**CONCLUSION:**

In accordance with the foregoing, it is respectfully submitted that all outstanding objections and rejections have been overcome and/or rendered moot, and further, that all

pending claims patentably distinguish over the prior art. Thus, there being no further outstanding objections or rejections, the application is submitted as being in condition for allowance which action is earnestly solicited.

If the Examiner has any remaining issues to be addressed, it is believed that prosecution can be expedited by the Examiner contacting the undersigned attorney for a telephone interview to discuss resolution of such issues.

If there are any underpayments or overpayments of fees associated with the filing of this Amendment, please charge and/or credit the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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